

**C. REMARKS**

**1. Status of the Claims**

Claims 1-21 are currently pending in the application. Claims 1 and 21 are independent. Claims 2-20 depend on claim 1.

Claim 1 has been amended, as explained in section 2 below.

New claims 22 and 23 have been added, as explained in section 7 below.

**2. Amendment to Claim 1**

Claim 1 has been amended, in order to correct an inadvertent typographical error, and for reasons having nothing to do with the patentability of claim 1, and having nothing to do with any of the Examiner's rejections.

In part C of claim 1, "said plurality of organisms" has been amended to read "said plurality of microorganisms," in order to correct the inadvertent typographical error, and to provide proper antecedent basis: note that earlier in claim 1, in part B, it is recited "said sample fluid having a plurality of **microorganisms** dispersed therein." (boldface added).

No new matter is added by this amendment, support for which is found throughout Applicant's specification.

**3. Rejection of Claims 1, 3-9, and 11-20 Under 35 U.S.C. § 103 (a)**

Claims 1, 3-9, and 11-20 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Pat. No. 5,157,261 to Grey et al. ("Grey") in view of published PCT Application WO 99/64903 to Broeng et al. ("Broeng"). Applicant respectfully traverses.

Applicant submits that, for the reasons discussed in detail below, the Examiner has failed to establish a *prima facie* case of obviousness of claims 1-5, 7-13, and 16-20 over Grey in view of Broeng, and therefore that the Examiner has failed to meet his initial burden of proof. See MPEP 2142 ("The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does

not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.”)

It is well known that, in order to establish a *prima facie* case of obviousness, a rejection must satisfy at least the following:

- A) The prior art reference(s) must teach or suggest all of the elements and limitations recited in the claims; and
- B) There must be some suggestion, teaching, or motivation to combine the references on which the rejection is based.

See MPEP 2142.

Applicant submits that the Examiner’s rejection of claims 1-5, 7-13, and 16-20 over Grey in view of Broeng satisfies none of the criteria above (neither A nor B).

**A) The Documents cited by the Examiner (Grey and Broeng),  
Either Alone or in Combination, Fail to Teach or Suggest All of the  
Elements of Claims 1-5, 7-13, and 16-20**

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The Examiner states (see page 10, lines 10-14 of the Office Action):

*“... the combination of the references of Grey et al. and Broeng et al. addresses these claim limitations. Note one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 624 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).”*

In response, Applicant submits that, for all of the reasons discussed in detail below, the combination of Grey and Broeng fails to teach or suggest at least elements 2) and 4) listed below, of claim 1. In other words, the combination of Grey and Broeng does not result in the invention claimed in claim 1, and therefore the combination of Grey and Broeng is not a proper basis for an obviousness rejection of claim 1.

Applicant respectfully submits that the combination of Grey and Broeng, fails to teach or suggest at least elements 2) and 4), among the elements of independent claim 1 that are listed below:

- 1) “a photonic band gap structure including an internal surface that defines a core

*region; wherein said internal surface of said photonic band gap structure is coated with a film formed of a plurality of molecules;"*

2) *"wherein in response to said excitation light, at least one of said plurality of organisms is capable of interacting with at least one of said plurality of molecules so as to generate a fluorescent signal;"*

3) *"an optical detector for detecting said fluorescence signal"; and*

4) *"said photonic band gap structure is adapted to guide said fluorescence signal through said core region and onto said detector for detection by said detector."*

Applicant submits that Grey does not teach elements 1), 2), and 4), whereas Broeng does not teach elements 2), 3) and 4), and that therefore the combination of Grey and Broeng fails to teach at least elements 2) and 4) listed above.

The Examiner has acknowledged that Grey does not teach elements 1) and 4) listed above, as noted earlier. See Office Action, page 3, lines 9-11 , (*"The above claims [1, 3-9, and 11-20] differ [from Grey] by reciting the use of a photonic band gap structure with an internal core region for supporting the coated molecules wherein the sample fluid is contacted or contained within the core region"*). Applicant further notes that Grey also does not teach, suggest, or mention that a photonic band gap structure be adapted to guide a fluorescence signal through the core region and onto the fluorescence detector, in contrast to the requirement of limitation 4) above.

Grey also does not teach element 2). Contrary to the Examiner's statement, Grey does not teach, suggest, or mention that microorganisms, dispersed within a sample fluid contained in the core region of the PBG structure, interact with at least one of the plurality of molecules forming the coating film so as to generate a fluorescent signal, in contrast to the limitation 2) above.

On the contrary, Grey teaches away from limitation 2).

See Tec Air, Inc. v. Denso Mfg. Mich. Inc., 192 F.3d 1353, 1360, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999): "A reference may be said to **teach away** when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant." Also, a prior art reference must be

considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert denied*, 469 US 851 (1984).

Applicant submits that Grey teaches away from limitation 2) above, because the interaction between TNT (the chemical within the fluid (air) whose presence is being detected in Grey) and a molecule compound, as disclosed in the Grey reference, not only does not generate a fluorescent signal, in violation of the requirement of limitation 2) above, but on the contrary reduces an already existing fluorescent intensity of the compound. See e.g., Grey col. 2, lines 29-44 ("... the present invention functions by affixing a[n already] fluorescent PAH compound at the distal end of an optical fiber or waveguide. . . . a decrease in fluorescence intensity indicates the presence of the explosive compounds . . . . A consequence . . . is . . . a decrease, or quenching, of the fluorescent intensity. . . . As a result of the interaction of the high explosive with the PAH, the fluorescent intensity of the PAH is reduced).(underlining added).

See also Grey Col. 6, line 64 - Col. 7, line 2.

. . . the air-borne explosive molecules interact with the PAH and reduce the fluorescence. The reduced fluorescence . . . is detected by the light sensing means.

The relative decrease in fluorescence can be extrapolated into a relative quantity of explosive mixture molecules. . . .

Accordingly, Grey teaches away from limitation 2) above by disclosing that the interaction between the affixed PAH and the air-borne molecules results in a "decrease," "quenching," or reduction of an already existing fluorescent activity, in direct contrast to generating fluorescence. Applicant submits that Grey teaches away from limitation 2) that requires an interaction that results in the generation of a fluorescent signal, because a person of ordinary skill, upon reading Grey, would be led in a direction divergent from the path that was taken by Applicant. The path taken by Applicant was to shine excitation light onto a sample fluid having dispersed therein microorganisms, so that the microorganisms would interact (in response to excitation light) with the molecules of a thin film coating in the interior surface of the PBG core

region so as to generate from scratch a fluorescent signal. Grey leads the person of ordinary skill in a direction divergent from such a path, because Grey teaches affixing PAH to a sensor, so that the substance being detected (an explosive), when interacting with the PAH, decreases or quenches the extant fluorescent activity of the PAH, so that the amount of decrease would be indicative of the presence of the explosive, in direct contrast with generating a fluorescent signal that is indicative of the presence of the substance of interest (i.e. a microorganism).

The Examiner states on page 9, lines 20-25: ". . . *the interaction of the PAH coating and TNT analyte of the reference of Grey et al. clearly generates a fluorescent signal. If not, how would the interaction of the PAH and TNT be monitored by the detector (spectrometer) and how would the concentration of TNT be determined if a detectable fluorescent signal is not generated by the interaction of PAH and TNT?*"

Applicant responds that, as explained above, Grey does not disclose any interaction of PAH and TNT that generates a fluorescence signal, but rather an interaction that decreases an extant fluorescent signal. The reason the concentration of TNT can be determined, even though a fluorescent signal is not generated by the interaction of PAH and TNT, is that the interaction of PAH and TNT does not wholly extinguish the extant fluorescent activity of PAH, although it does reduce (by a detectable amount) such fluorescent activity. The amount of decrease in fluorescent activity, given by the difference between the amount of fluorescence measured before the interaction between PAH and TNT, and the amount of fluorescence measured after the decrease in fluorescence activity induced by the interaction between PAH and TNT, is used in Grey as a indicator of the presence of the explosives being detected.

In sum, Grey does not teach limitations 1), 2), and 4) above.

As for Broeng, which is directed to PBG (photonic band gap) waveguiding structures, Broeng does not teach elements 2), 3) and 4) above.

Regarding element 2) above, nowhere does Broeng teach or suggest that the core region of the photonic band gap structure contain any microorganism that is capable of interacting with any of the molecules of a thin film coating the internal surface of the photonic band gap structure, so as to generate a fluorescent signal.

Regarding element 3) above, nowhere does Broeng teach or suggest an optical detector for detecting the fluorescent signal.

Regarding element 4) above, nowhere does Broeng teach or suggest that a photonic band gap structure be adapted to guide a fluorescent signal, generated by an interaction between a microorganism and a molecule of the thin film coating the interior surface of a photonic band gap fiber, through a core region of the photonic band gap structure and onto an optical detector.

In sum, for the reasons outlined above, Grey fails to teach elements 1), 2), and 4) above, and Broeng fails to teach elements 2), 3), and 4). Accordingly, Applicant concludes that the proposed combination of Grey and Broeng does not teach or suggest at least elements 2) and 4) of claim 1.

Because the proposed combination of Grey and Broeng does not teach or suggest all the elements of claim 1, the proposed combination is not a proper basis for an obviousness rejection of claim 1.

**B) There is no Suggestion, Teaching, or Motivation to Combine the Documents (Grey and Broeng) on which the Examiner's Rejection is Based**

Applicant submits that, not only does the proposed combination of Grey and Broeng fail to teach or suggest all the limitations of claim 1, but also there is no suggestion within the cited documents Grey and Broeng of any desirability of making such a combination, nor is there any teaching or motivation for such a combination.

It is well established that the Examiner must provide some suggestion of the desirability of doing what the inventor has done, without the benefit of impermissible hindsight. See MPEP 2142 and In Re San Su Lee, 277 F.3d at 1338: "*The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.*" The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). See MPEP 2143.01.

It is also well established that, in order for a *prima facie* case of obviousness to

be established, the teaching or suggestion to make the claimed combination must be found in the prior art itself, or in the knowledge of one skilled in the art at the time of the invention, and not based on applicant's disclosure. In Re San Su Lee, 277 F.3d 1338 (CAFC 2002) ("*[T]he evidence of record must identify an objective source of the motivation to combine A with B in the manner proposed.*") See also MPEP §§ 2141 – 2142.

Applicant respectfully submits that, for reasons explained below, the record does not establish the requisite motivation for combining Grey with Broeng, because i) nowhere in the Grey and Broeng documents themselves is there any suggestion of the desirability of making the proposed combination; ii) the knowledge available to one of ordinary skill in the art does not provide such a suggestion.

Applicant submits that nothing in Grey (which is directed to detecting explosives by attaching an element (PAH) which, when excited with radiation, decreases extant fluorescent activity) suggests the desirability of using excitation light to cause an interaction that generates (rather than reducing the extant intensity of) fluorescent light.

As explained above, on the contrary Grey teaches away from causing the generation of fluorescence by an interaction (in response to excitation light) between a coating on the internal surface of the optical fiber and the microorganism of interest. Further, nothing in Grey suggests the desirability of using photonic band gap fibers to detect the fluorescence that is so generated. As for Broeng, nothing in Broeng suggests the desirability of using photonic band gap fibers to detect fluorescence. In particular, nothing in Broeng suggests coating an inner surface of a core region of a photonic band gap fiber with a thin film of molecules (e.g. conjugate polymers) that interact (in response to excitation light) with substances of interest (e.g. microorganisms) within the core in a way as to result in the generation of fluorescent light.

The Examiner states: (see page 10, lines 15-23 of the Office Action): "*The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.*"

*See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.3d 1347, 7J 1 21 USPQ2d 1941 (Fed Cir. 1992). In this case, the Examiner is of the position that the disclosure of the reference of Broeng et al. would have suggested to one of ordinary skill in the art that the substitution of a photonic band gap waveguide for an optical fiber waveguide would have been obvious for the advantages associated with the use of a photonic band gap waveguide. See page 3, lines 23-38, and page 5, lines 18-24, of Broeng et al. which suggest the use of band gap fibers (hollow core fibers) in sensor systems.*

Applicant submits that the above statements by the Examiner do not provide any suggestion as to why the particular **proposed combination** of references would be desirable (either because of the contents of the references themselves, or because of the knowledge available to one of skill in the art), thus failed to meet his initial burden. Applicant also submits that by failing to consider the invention as a whole, the Examiner uses impermissible hindsight reconstruction. Applicant's invention is not limited merely to the substitution of a photonic band gap waveguide for an optical fiber waveguide (the desirability for which, according to the Examiner, is suggested by the knowledge generally available to one of skill in the art). Substituting a photonic band gap waveguide for an optical fiber waveguide does not result in Applicant's invention as a whole, in particular does not result in the invention as claimed in claim 1. Applicant's claim 1 contains many more limitations, as described in detail in section 3 B) above, including but not limited to the coating of an internal surface of the core region of a photonic band gap fiber with a thin film of molecules, and generating excitation light directed to a sample fluid (having microorganisms dispersed therein) contained within the core region so as to cause an interaction between the molecules and the micororganisms in a way as to generate fluorescent light.

A basic tenet of an obviousness rejection is that the references must be viewed without the benefit of impermissible hindsight. MPEP 2141. Applicant submits that the Examiner used impermissible hindsight, in his 35 USC 103 rejection of claim 1 in view of Grey and Broeng. More specifically, by using Applicant's disclosure as a roadmap,



and by failing to consider the invention as a whole and also failing to consider the references as a whole, the Examiner used hindsight reconstruction, which is impermissible under MPEP 2141.

The fact that substituting a photonic band gap waveguide for an optical fiber waveguide is advantageous is not sufficient to suggest the desirability of combining the **Grey** and **Broeng** documents. The advantages of PBG waveguides discussed on page 3, lines 23-38, of Broeng, namely that by using PBG materials, the optical fiber core need not have a higher index of refraction than the cladding, are not relevant to the explosives detector of Grey, because 1) Grey does not teach or disclose any cladding, nor any core, 2) nor does Grey teach or disclose that an optical fiber core has a higher index of refraction compared to the cladding, 3) nor is there any slightest hint in Grey that optical fiber cores having a lower index of refraction compared to the cladding would in any way be advantageous.

Accordingly, the fact that lower-index core optical fibers, made possible by photonic band gaps, may be advantageous, does not suggest any desirability of combining the photonic band gap optical waveguide of Broeng with the explosives detector of Grey.

For these reasons, there is no teaching, suggestion, or motivation to combine Grey and Broeng, either in the references themselves nor in the knowledge generally available in the art. Therefore, Applicant submits that the Examiner has failed to meet his burden of providing a suggestion of the desirability of making the proposed combination.

Further, even if the references were so combined, the proposed combination does not teach all the elements of Applicant's claim 1, because the proposed combination does not teach at least above-listed elements 2) and 4) of claim 1, as explained in section A) above.

For all of the reasons discussed above, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, and that there is no proper basis for the 35 U.S.C. §103 rejection of independent claim 1 which is not rendered obvious by Grey and Broeng, either alone or in combination. Applicant

submits that independent claim 1 is allowable, and that claims 2-5, 7-13, and 16-20 (which depend on claim 1 and hence include all the limitations of claim 1) is allowable, at least as depending from an allowable base claim.

**4. Rejection of Claims 1-5, 7-13, and 16-20 Under 35 U.S.C. § 103 (a)**

Claims 1-5, 7-13, and 16-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,496,700 to Ligler et al. ("Ligler") in view of Broeng.

Applicant submits that the Examiner's rejection of claims 1-5, 7-13, and 16-20 over Ligler in view of Broeng does not establish a *prima facie* case of obviousness, at least because the rejection does not satisfy the following criteria:

- A) The prior art reference(s) must teach or suggest all of the elements and limitations recited in the claims; and
- B) There must be some suggestion, teaching, or motivation to combine the references on which the rejection is based.

Applicant submits that the Examiner's rejection of claims 1-5, 7-13, and 16-20 under 35 U.S.C. 103 over Ligler and Broeng satisfies none of the criteria above (neither A) nor B)).

**A) The Documents cited by the Examiner (Ligler and Broeng), Either Alone or in Combination, Fail to Teach or Suggest All of the Elements of Claims 1-5, 7-13, and 16-20**

Applicant respectfully submits that neither Ligler nor Broeng, either alone or in combination, teaches or suggests the subject matter of independent claims 1-5, 7-13, and 16-20. In particular, Applicant submits that the combination of Ligler and Broeng fails to teach or suggest at least elements 3), 4), and 5) among the following elements of independent claim 1:

- 1) *"a photonic band gap structure including an internal surface that defines a core region; wherein said internal surface of said photonic band gap structure is coated with a film formed of a plurality of molecules";*
- 2) *"a sample fluid contained within said core region, said sample fluid having a plurality of microorganisms dispersed therein";*

- 3) *"wherein in response to said excitation light, at least one of said plurality of organisms is capable of interacting with at least one of said plurality of molecules so as to generate a fluorescent signal;"*
- 4) *"an optical detector for detecting said fluorescence signal"; and*
- 5) *"said photonic band gap structure is adapted to guide said fluorescence signal through said core region and onto said detector for detection by said detector."*

Applicant submits that Ligler does not teach elements 1), 2), 3), 4) and 5) above, for reasons explained below, and that Broeng does not teach elements 3), 4), and 5), as explained in section 2A) above, and therefore concludes that the proposed combination of Ligler and Broeng fails to teach at least elements 3), 4), and 5) listed in the previous paragraph.

The Examiner has acknowledged that Ligler does not teach or suggest limitations 1) and 2) above. See Office Action page 5, lines 6-8 (*"The above claims differ [from Ligler] by reciting the use of a photonic band gap structure with an internal core region for supporting the coated molecules wherein the sample fluid is contacted or contained within the core region."*). The Examiner has thus acknowledged that Ligler does not teach or suggest any photonic band gap structure wherein the internal surface is coated with a film formed of a plurality of molecules, i.e. that limitation 1) above is missing in Ligler. The Examiner has also acknowledged that Ligler does not teach or suggest any sample fluid contained within the core region and having a plurality of microorganisms dispersed therein.

Ligler also does not teach elements 3), 4), and 5) above. Ligler is directed to an optical immunoassay system for detecting the presence of microbial analytes in a sample. The sample is dyed and brought into contact with an optical fiber waveguide, the outer surface of which has capture molecules attached thereon. If the dyed sample contains the microbial analyte whose presence is being investigated, the capture molecule, the dye, and the analyte form a complex, which can be excited so that an optical signal is generated and detected.

Nowhere in Ligler is there any teaching or suggestion of generating of a

fluorescent signal through the interaction (in response to excitation light) of the molecules, coated onto the internal surface of a core region defined by a photonic band gap structure, with microorganisms dispersed within the sample fluid contained in the core region. In other words, limitation 3) is missing in Ligler. Nowhere in Ligler is there any teaching or suggestion of a detector for detecting fluorescent light. In other words, limitation 4) is missing in Ligler. Finally, nowhere in Ligler is there any teaching or suggestion of a photonic band gap structure that is adapted to guide a fluorescent signal, generated in the manner recited in limitation 3), through the core region and onto a fluorescence detector. In other words, limitation 5) is missing in Ligler.

In sum, Ligler does not teach or suggest all of the limitations 1), 2), 3), 4), and 5) above.

Further, Broeng does not teach elements 3), 4) and 5) above, as explained in detail in section 3 A) above. In particular, regarding element 3) above, nowhere does Broeng teach or suggest that the core region of the photonic band gap structure contains any microorganism that is capable of interaction with any of the molecules of a thin film coating the internal surface of a photonic band gap structure. Regarding element 4) above, nowhere does Broeng teach or suggest an optical detector for detecting a fluorescent signal generated in this manner. Regarding element 5) above, nowhere does Broeng teach or suggest that a photonic band gap structure be adapted to guide the fluorescent signal (generated by an interaction, in response to excitation light, between a microorganism and a molecule of the thin film coating the interior surface of a photonic band gap fiber) through a core region of the photonic band gap structure and onto an optical detector.

Because Ligler fails to teach or suggest limitations 1), 2), 3), 4), and 5) of claim 1, and Broeng fails to teach or suggest limitations 3), 4), and 5), the proposed combination of Ligler and Broeng does not teach or suggest at least elements 3), 4), and 5) of claim 1.

Because the proposed combination of Ligler and Broeng does not teach or suggest all the elements of claim 1, the proposed combination is not a proper basis for an obviousness rejection of claim 1.

**B) There is no Suggestion, Teaching, or Motivation to Combine the Documents (Ligler and Broeng) on which the Examiner's Rejection is Based, and such a Combination Improperly Changes the Principle of Operation of Ligler**

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Not only does the proposed combination of Ligler and Broeng fail to teach or suggest all the limitations of claim 1, but also there is no suggestion, teaching, or motivation to combine the Ligler and Broeng documents in the manner proposed by the Examiner.

As explained in section 3 B), the Examiner has the initial burden of providing some suggestion of the desirability of doing what the inventor has done, without the benefit of impermissible hindsight. It is also well established that, in order for a *prima facie* case of obviousness to be established, the teaching or suggestion to make the claimed combination must be found either in the prior art itself, or in the knowledge of one skilled in the art at the time of the invention, and cannot not based on applicant's disclosure. The evidence of record must identify an objective source of the motivation to combine A with B in the manner proposed.

Applicant respectfully submits that, for reasons explained below, the record does not establish the requisite motivation for combining Ligler with Broeng, and the Examiner failed to meet his burden. Therefore, no *prima facie* case of obviousness has been established for the Examiner's 103 rejection of claim 1 over Ligler and Broeng.

In particular, Applicant submits that 1) nowhere in the Ligler and Broeng documents, and nowhere in the knowledge available to one of ordinary skill in the art at the time of the invention, is there any suggestion of the desirability of making such a combination; and 2) the proposed combination impermissibly changes the principle of operation of Ligler.

Nothing in Ligler suggests the desirability of using a photonic band gap fiber defining an internal core region coated with the film of molecules to perform the desired immunoassay. Nothing in Ligler suggests the desirability of introducing a sample fluid containing substances of interest (e.g. microorganisms), and shining excitation light onto a fluid so as to induce an interaction between the molecules of the film coating the PBB internal surface and the microorganisms in a way as to create a fluorescence

signal.

On the contrary, Ligler **teaches away** from these features. As well known, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. In Ligler, the optical waveguide (e.g. the fiber optic waveguide) has no internal surface that defines a core region and in particular does not have any internal surface coated with any film of molecules. In contrast, as shown in Ligler Figure 2, the outer surface of the fiber optical waveguide disclosed in Ligler is coated with antibodies, not its internal surface. No optical waveguide having any hollow core region is disclosed in Ligler.

Also, Ligler does not teach or suggest anywhere any sample fluid that is contained within a core region of any optical structure. Ligler teaches away from the limitations in claim 1 requiring “. . . *an internal surface that defines a core region. . . a sample fluid contained within said core region, said sample fluid having a plurality of microorganisms dispersed therein,*” because Ligler states that the sample fluid is introduced over a molecule-coated structure, rather than the sample being contained within a core region defined by an internal coated surface of the structure. See Ligler Col. 6, lines 64-66 (“. . . the stained sample is introduced over a solid support coated with a capture molecule specific for the microbial analyte of interest.”)

As for Broeng, there is no teaching, suggestion, or mention in Broeng of the desirability of detecting fluorescence emission, and in particular there is no teaching, suggestion, or mention of coating an internal surface of a core region of a PBG structure with molecules capable of interacting with the substances of interest (being detected) so as to generate a fluorescent signal.

The Examiner states, on page 12, lines 13-21 of the Office Action:  
*“the Examiner has relied upon the combined teaches [sic] of the references of Ligler et al. and Broeng et al. to suggest to one of ordinary skill in the art that the use of a photonic band gap structure would have been advantageous over the fiber optic structure of the reference of Ligler et al. In view of this suggestion and the disclosure of the reference of Broeng et al., one of ordinary skill in the art would have readily*

*recognized that when using a photonic band gap structure, the coating and fluid sample would be employed within the core of the PBG structure. . . . the reference of Broeng . . . where it is disclosed that when using a PBG structure, the fluid sample is held and analyzed within the hollow core of the PBG structure.*

The Examiner further states, on page 13, lines 4-9 of the Office Action:  
*"In this case, the Examiner is of the position that the disclosure of the reference of Broeng et al. would have suggested to one of ordinary skill in the art that the substitution of a photonic band gap waveguide of an optical fiber waveguide would have been obvious for the advantages associated with the use of a photonic band gap waveguide. See page 3, lines 23-38, and page 5, lines 18-24, of Broeng et al. which suggest the use of band gap fibers (hollow core fibers) in sensor systems."*

Applicant responds that the above statements by the Examiner fail to meet the Examiner's burden of suggesting the desirability of combining Ligler and Broeng. The Examiner has failed to consider the invention as a whole, because merely substituting a photonic band gap waveguide (disclosed in Broeng) for the optical fiber waveguide of Ligler does not result in Applicant's invention. The result of such a combination would lack at least the following features of Applicant's invention as claimed in claim 1: 1) an internal surface of a core region of the photonic band gap structure that is coated with molecules adapted to interact with microorganisms dispersed in a fluid in a way as to generate a fluorescent signal; 2) using a photonic band gap waveguide to guide the fluorescent signal so generated, onto a fluorescence detector.

A basic tenet of an obviousness rejection is that the references must be viewed without the benefit of impermissible hindsight. MPEP 2141. Applicant submits that the Examiner used impermissible hindsight, in his 35 USC 103 rejection of claim 1 in view of Ligler and Broeng, by failing to consider the invention as a whole, by failing to consider the references as a whole, and by using Applicant's disclosure as a roadmap.

The fact that substituting a photonic band gap waveguide for an optical fiber waveguide is advantageous does not suggest the desirability of combining the **Ligler** and **Broeng** documents (the combination of which does not result in Applicant's

invention, anyway). The advantages of PBG waveguides discussed on page 3, lines 23-38, of Broeng, namely that by using PBG materials, the optical fiber core need not have higher index than the cladding, are not relevant to the immunoassay system of Ligler, because 1) Ligler does not teach or disclose any cladding, nor any optical fiber core, 2) nor does Ligler teach or disclose any optical fiber core having a higher index of refraction compared to the cladding, 3) nor is there any slightest hint in Ligler that optical fiber cores having a lower index of refraction compared to the cladding would in any way be advantageous.

Accordingly, the fact that lower-index core optical fibers, made possible by photonic band gaps, may be advantageous, does not suggest any desirability of combining the photonic band gap optical waveguide of Broeng with the immunoassay system of Ligler, because neither the desirability of such features nor any motivation for including such features are provided in Ligler.

Applicant further notes that the proposed combination of Ligler and Broeng in the manner suggested by the Examiner is improper and contrary to the precepts of MPEP 2143.01, which mandates that the proposed modification cannot change the principle of operation of a reference. The proposed combination (of Ligler and Broeng) impermissibly changes the principle of operation of the device disclosed in Ligler, from attaching capture molecules on the outer surface of an optical waveguide and bringing the sample into contact with the capture molecules (as disclosed in Ligler), to enclosing a fluid containing the samples within a hollow core region of the optical fiber (as disclosed in Broeng).

For these reasons, not only is there a lack of an objective source of any motivation to combine Ligler with Broeng, but also such a combination would be improper under MPEP 2143.01.

For all of the reasons discussed above, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, and that there is no proper basis for the 35 U.S.C. §103 rejection of independent claim 1 which is not rendered obvious by Ligler and Broeng, either alone or in combination. Applicant submits that independent claim 1 is allowable, and that claims 1-5, 7-13, and 16-20



(which depend on claim 1 and hence include all the limitations of claim 1) is allowable, at least as depending from an allowable base claim.

**5. Rejection of Claim 21 Under 35 U.S.C. § 103 (a)**

Claim 21 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Grey in view of Broeng taken further in view of either U.S. Pat. No. 5,250,264 to Walt et al. ("Walt") or U.S. Pat. No. 5,690,894 to Pinkel et al. ("Pinkel").

Applicant respectfully traverses, and submits that neither Grey nor Broeng nor Walt nor Pinkel, alone or in combination, teaches or suggests the subject matter recited in claim 21.

In particular, the combination of these references fails to teach, mention, or suggest at least the following limitations of claim 21:

- 1) *"an array of photonic band gap fibers, each photonic band gap fiber including an internal surface that defines a hollow core region;"*
- 2) *"wherein each internal surface of each photonic band gap fiber is coated with a film formed of a plurality of conjugated polymer molecules;"*
- 3) *"wherein in response to said excitation light at least one of said plurality of sample organisms is capable of binding with at least one of said plurality of conjugated polymer molecules so as to generate a fluorescence signal"; and*
- 4) *"wherein each photonic band gap fiber is adapted to guide said fluorescence signal through said core region and onto said detector for detection by said detector."*

For reasons already discussed above, the combination of **Grey** and **Broeng** fails to teach or suggest limitations 1) – 4) above, i.e. fails to teach or suggest any coating of molecules onto an internal surface of a PBG structure so that upon directing of excitation light onto substances of interest (microorganism), they interact with these coated molecules so as to generate a fluorescent signal. Neither **Walt** nor **Pinkel** corrects this deficiency, because neither reference teaches these features of Applicant's invention, as acknowledged by the Examiner, who states (page 16, lines 11-13 of the Office Action) that *"The references of Walt et al. and Pinkel et al. where [sic]*

*cited merely as tertiary references that disclose to one of ordinary skill in the art that the use of arrays of optical sensing devices is conventional in the art."*

(**Walt** relates to fiber optic arrays for detecting multiple analytes in a sample, by concurrently using a plurality of different dyes attached upon the (outer) surface of the sensor. See e.g. Walt Col. 16, lines 21-26 ("The unique fiber optical sensor of the present invention requires that one or more light energy absorbing dyes and/or dye mixtures be disposed individually at different spatial positions upon the optical array surface . . . ."). **Pinkel** relates to biosensors including a plurality of optical fibers, each optical fiber having attached at one end molecules that can function as binding partners.)

There is no teaching, suggestion, or mention anywhere in Walt or Pinkel (either alone or in combination) of 1) the coating of an internal surface of a core region of a photonic band gap fiber with a film formed of molecules; 2) the generation of a fluorescent signal by the interaction of microorganisms dispersed within a fluid in the core region with the molecules; and 3) the guidance of such a fluorescent signal onto a detector by the photonic band gap fiber. Therefore, neither Walt nor Pinkel corrects the above-mentioned deficiency of the combination of Grey and Broeng.

For these reasons, the combination of Grey, Broeng, Walt and Pinkel fails to teach or suggest the above-listed elements 1), 2), 3) and 4) of claim 21.

Also, nowhere in the four cited documents (Grey, Broeng, Walt and Pinkel), and nowhere in the knowledge generally available to one skilled in the art, is there any teaching or suggestion of the desirability of making such a combination of the four references (which does not result in Applicant's invention, anyway). As explained above, the advantages of PBG waveguides discussed on page 3, lines 23-38, of Broeng, namely that by using PBG materials, the optical fiber core need not have higher index than the cladding, are not relevant to the explosives detection system of Grey, which does not mention any core or any cladding or any relative strength therebetween of refractive indices. These advantages are also irrelevant to the devices disclosed in Walt and Pinkel, which also do not mention any cores or claddings or

relative strengths therebetween of refractive indices. Therefore, the advantages of PBG waveguides, described in Broeng, provide no motivation to one of ordinary skill in the art to combine the four cited references.

For these reasons, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness, and that there is no proper basis for the 35 U.S.C. § 103 rejection of claim 21, which is not rendered obvious by Grey, Broeng, Walt, and Pinkel, either alone or in combination. Applicant respectfully submits that claim 21 is allowable.

**6. Rejection of Claim 21 Under 35 U.S.C. § 103 (a)**

Claim 21 has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Ligler** in view of **Broeng** taken further in view of either **Walt** or **Pinkel**. Applicant respectfully traverses.

Applicant submits that the proposed combination of references (Ligler, Broeng, Walt/Pinkel) fails to teach or suggest all the elements of claim 21. Applicant further submits that the Examiner failed to meet his burden of providing some suggestion of the desirability of making such a combination.

The proposed combination of Ligler, Broeng, Walt and Pinkel fails to teach or suggest at least the following elements of claim 21:

- 1) *"an array of photonic band gap fibers, each photonic band gap fiber including an internal surface that defines a hollow core region;"*
- 2) *"wherein each internal surface of each photonic band gap fiber is coated with a film formed of a plurality of conjugated polymer molecules;"*
- 3) *"wherein in response to said excitation light at least one of said plurality of sample organisms is capable of binding with at least one of said plurality of conjugated polymer molecules so as to generate a fluorescence signal"; and*
- 4) *"wherein each photonic band gap fiber is adapted to guide said fluorescence signal through said core region and onto said detector for detection by said detector."*

As discussed in section 3A) above, the combination of Ligler and Broeng fails to

teach or suggest at least elements 3) and 4) above. Both Walt and Pinkel fail to correct this deficiency. There is no teaching, suggestion, or mention in both Walt and Pinkel, either alone or in combination, of: 1) the generation of a fluorescent signal by the interaction of microorganisms with the molecules forming a film that coats an internal surface of a core region of a photonic band gap fiber; and 2) the guidance of such a fluorescent signal onto a detector by the photonic band gap fiber.

Further, for reasons discussed in section 5 above, there is no motivation or any suggestion of the desirability of making such a combination, either in the references themselves, or in the knowledge available to one of ordinary skill in the art.

Accordingly, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness, because 1) nowhere in any of the cited references (Ligler, Broeng, Walt, Pinkel), and nowhere in the knowledge available to one of ordinary skill in the art, is there any suggestion, teaching, or motivation to combine the references on which the rejection is based; and 2) even if the references were so combined, the combination of Ligler, Broeng, Walt, and Pinkel fails to teach all of the elements and limitations recited in claim 21, as explained above.

For these reasons, it is submitted that there is no proper basis for the 35 U.S.C. § 103 rejection of claim 21, which is not rendered obvious by Ligler, Broeng, Walt, and Pinkel, either alone or in combination. Applicant respectfully submits that claim 21 is allowable.

## **7. New claims**

New claims 22-23 have been added, for reasons having nothing to do with any of the Examiner's rejections, and for reasons having no relation at all to the patentability of pending claims 1-21.

New claims 22-23 have been added because Applicant realizes that existing claims 1-21 have not defined Applicant's invention broadly enough, and that claims containing less limitations can properly define Applicant's invention.

No new matter is added by these new claims, support for which can be found

throughout Applicant's specification.

**8. Conclusion**

On the basis of the foregoing amendments, Applicant respectfully submits that all of the pending claims 1-23 are in condition for allowance. An early and favorable action is therefore earnestly solicited. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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